FDA Sheds Light on Sunscreens

The Food and Drug Administration (FDA) is taking steps to help protect consumers from skin damage caused by excessive sun exposure.

The new measures include the following:

- final regulations that establish standards for testing the effectiveness of sunscreen products and require labeling that accurately reflects test results
- a proposed regulation that would limit the maximum SPF value on sunscreen labeling to "SPF 50+"
- a data request for safety and effectiveness information for sunscreen products formulated in certain dosage forms (e.g., sprays)
- a draft guidance for sunscreen manufacturers on how to test and label their products in light of these new measures.

These measures are necessary, says Lydia Velazquez, PharmD, in FDA's Division of Nonprescription Regulation Development, because "our scientific understanding has grown. We want consumers to understand that not all sunscreens are created equal."

"This new information will help consumers know which products offer the best protection from the harmful rays of the sun," Velazquez says. "It is important for consumers to read the entire label, both front and back, in order to choose the appropriate sunscreen for their needs."

Everyone is potentially susceptible to sunburn and the other detrimental effects of exposure to UV radiation.

FDA's Final Regulations

The final regulations, which become effective in one year, establish a standard test for over-the-counter (sold without a prescription) sunscreen products that will determine which products are allowed to be labeled as "Broad Spectrum."

Products that pass this test will provide protection against both ultraviolet B radiation (UVB) and ultraviolet A radiation (UVA). Sunburn is primarily caused by UVB. Both UVB and UVA can cause sunburn, skin cancer, and premature skin aging. A certain percentage of a broad spectrum product's total protection is against UVA.

Under the new regulations, sunscreen products that protect against all types of sun-induced skin damage will be labeled "Broad Spectrum" and "SPF 15" (or higher) on the front.

The new labeling will also tell consumers on the back of the product that sunscreens labeled as both "Broad Spectrum" and "SPF 15" (or higher) not only protect against sunburn, but, if used as directed with other sun protection measures, can reduce the risk of skin cancer and early skin aging. For these broad spectrum products, higher SPF (Sun Protection Factor) values also indicate higher levels of overall protection.

By contrast, any sunscreen not labeled as "Broad Spectrum" or that has an SPF value between 2 and 14, has only been shown to help prevent sunburn.

Reynold Tan, a scientist in FDA's Division of Nonprescription Regulation Development, notes that FDA has been

developing testing and labeling requirements for sunscreen products for decades. However, only recently have the data become sufficient to establish an accurate and reliable test for broad spectrum UV protection, he says.

To help consumers select and use sunscreens appropriately, the final regulations include these additional labeling provisions:

- Sunscreen products that are not broad spectrum or that are broad spectrum with SPF values from 2 to14 will be labeled with a warning that reads: "Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."
- Water resistance claims on the product's front label must tell how much time a user can expect to get the declared SPF level of protection while swimming or sweating, based on standard testing. Two times will be permitted on labels: 40 minutes or 80 minutes.
- Manufacturers cannot make claims that sunscreens are "waterproof" or "sweatproof, or identify their products as "sunblocks." Also, sunscreens cannot claim protection immediately on application (for example, "instant protection") or protection for more than two hours without reapplication, unless they submit data and get approval from FDA.

Drug Facts

Active Ingredients — **Purpose**
Avobenzone 3%
Homosalate 10%
Octyl methoxycinnamate 7.5% } Sunscreen

Uses
- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions
- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients
aloe extract, barium sulfate, benzyl alcohol, carbomer, dimethicone, disodium EDTA, jojoba oil, methylparaben, octadecene/MA copolymer, polyglyceryl-3 distearate, phenethyl alcohol, propylparaben, sorbitan isostearate, sorbitol, stearic acid, tocopherol (vitamin E), triethanolamine, water

Other information
- protect this product from excessive heat and direct sun

Questions or comments?
Call toll free 1-800-XXX-XXXX

FDA Proposed Regulations, Data Requests, and a Draft Guidance

In addition to the final regulations, FDA is proposing a regulation that would require sunscreen products that have SPF values higher than 50 to be labeled as "SPF 50+." FDA does not have adequate data demonstrating that products with SPF values higher than 50 provide additional protection compared to products with SPF values of 50.

FDA is requesting data and information on different dosage forms of sunscreen products. The agency currently considers sunscreens in the form of oils, creams, lotions, gels, butters, pastes, ointments, sticks, and sprays to be eligible for potential inclusion in the OTC sunscreen monograph – meaning that they can be marketed without individual product approvals.

The agency currently considers wipes, towelettes, powders, body washes, and shampoo not eligible for the monograph. Therefore, they cannot be marketed without an approved application.

For sunscreen spray products, the agency requests additional data to establish effectiveness and to determine whether they present a safety concern if inhaled unintentionally. These requests arise because sprays are applied differently from other sunscreen dosage forms, such as lotions and sticks.

FDA is also issuing a draft guidance to help sunscreen manufacturers understand how to label and test their products in light of the final and proposed regulations and the data request on dosage forms. Tan says the FDA hopes that manufacturers will implement the new rules well before their effective date.

Comments on these proposals may be submitted at *www.regulations.gov* (docket number FDA-1978-N-0018).

Sun Safety Tips

Spending time in the sun increases the risk of skin cancer and early skin aging. To reduce this risk, consumers should regularly use sun protection measures including:

- Use sunscreens with broad spectrum SPF values of 15 or higher regularly and as directed.
- Limit time in the sun, especially between the hours of 10 a.m. and 2 p.m., when the sun's rays are most intense.
- Wear clothing to cover skin exposed to the sun; for example, long-sleeved shirts, pants, sunglasses, and broad-brimmed hats.
- Reapply sunscreen at least every 2 hours, more often if you're sweating or jumping in and out of the water.

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*